STATEMENT OF WORK

SCOPE OF CONTRACT

The scope of this contract is to provide logistical, technical, management, and dosimetric support for the Radiation Epidemiology Branch (REB) to conduct important multidisciplinary studies of radiation-related cancer and other health outcomes in an operationally efficient and scientifically sound manner.

REB conducts approximately 8-30 studies per year. Approximately 15 investigators from REB will be leading the studies.

TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to simultaneously manage concurrent, multiple, domestic and international studies.

TASK AREA I –Phase-in

Upon award, the draft initial transition plan shall be revised, if necessary, and the draft initial transition plan submitted with the Contractor's proposal will become the final initial transition plan upon approval of the Contracting Officer's Representative (COR). The initial transition plan shall delineate the following:

- transition activities to be undertaken
- timelines for the completion of each transition activity
- staff to be assigned

Resource materials provided by the incumbent Contractor to the Contractor will include:

- Study protocols
- Standard Operating Procedures
- Data collection forms
- Coding manuals
- Data files – electronic and hard copy (as approporiate)
- Decision logs
- List of critical data files
- QC/QA plan
- Tracing files
- All other relevant study documentation

The final initial transition plan shall be followed to ensure an orderly, secure, efficient, and expedient transition of all contract activities. The Contractor shall conduct orientation briefings for NCI Lead Project Investigators and Contractor Key Personnel and participate in one full-day contract initiation meeting with:

- NCI COR
- Contracting Officer
- Other NCI staff designated by the NCI COR
- Contractor personnel
- Incumbent Contractor personnel

Should an initial transition be required, the transition period shall be from August 20, 2014 through September 19, 2014.

TASK AREA II – REB Core Support Services

The REB Core Support Services consist of the provision of broad-based, centralized, and fully integrated operational, administrative, regulatory, and logistical support services to all REB studies.

There are five major sections to Task Area II:

1. Project Management of Ongoing Studies
2. Radiation Dosimetry Work of Ongoing Studies
3. Specimen Collection with Samples
4. Data Preparation and Processing
5. Pilot/Feasibility Studies

1. Project Management of Ongoing Studies

a. The Project Director and Senior Study Managers shall meet monthly with the NCI COR in face to face and/or teleconference meetings to review contract performance and discuss project management issues. As needed, other points of contact will be included to review progress and priorities, and discuss strategies and plans.

b. The Contractor shall arrange for communications and meetings as needed between the NCI Lead Project Investigators, other NCI contractors, collaborating institutions, and/or agents for those whose cooperation or approval is necessary. Coordinate and attend such meetings, which may include domestic or international travel, provide required background material, keep minutes of such meetings, prepare lists of action items, and take appropriate actions on recommendations, as applicable.

c. The Contractor shall respond to priority requests from the COR and changes of study direction rapidly by appropriate activities and use of personnel.

d. At the outset and throughout the progress of each study, the relevant NCI Lead Project Investigator, with advice from the COR, will approve a plan prepared by the Senior Study Manager for the schedule and contents of reports needed for quality control. Quality control shall require that the Contractor:

1. Document each step of a study and maintain, in an orderly arrangement, all relevant material, so that any aspect of the study may be reviewed and evaluated by the NCI staff at any point in time. Involved are the following: prepare and/or print letters, forms, summaries of meetings, and other documents necessary for the conduct of the study; duplicate study documents when the original sources cannot be retained; maintain a filing system of all materials relevant to the study, cross-referenced in a manner so as to make all of the material easily accessible (these materials shall be maintained under security in accordance with requirements of the Privacy Act as it applies to Contractors); and maintain a log of decisions made during each study that affect the design, conduct, or analysis; each entry shall include a brief explanation

and date of the problem, the decision made, and the name of the NCI investigator who authorized the change.

2. Support and manage internal electronic or paper (as needed) record-keeping procedures for assessing the progress of data collection, data preparation, and data entry.

3. Support and manage spreadsheet and internal monitoring systems to track the status of subject contact and recruitment. Interact with recruitment study sites on a regular basis, including an annual site visit to aid in monitoring and recruitment and study procedures.

4. Report verification rates, discrepancy rates, and error rates to NCI Lead Project Investigator for data collection (error rate <5%), preparation (error rate <5%), and keying (error rate <1%), following the schedule agreed upon with the NCI Lead Project Investigator. Any unusual problems should be brought to the immediate attention of the NCI COR.

5. For laboratory or data collections, support and manage spreadsheet and internal monitoring systems to track the status of specimens and/or data. Coordinate to ship specimens back to the NCI repository specified by the COR in accordance with Section D after the assays have been completed. On a regular basis, to be decided by the COR or the relevant NCI investigator, verify the status of specimens at the repository.

6. Provide complete documentation to accompany data file deliveries to the NCI Lead Project Investigator. Complete documentation includes, but is not limited to, coding manuals, data dictionaries and a final printed report describing data collection activities.

e. The Contractor shall inform the NCI COR as soon as it is aware of any unforeseen circumstances that may delay timely completion or progress of study activities. All study activities, documents, and procedures must be approved by the NCI COR prior to implementation.

2. Radiation Dosimetry Work of Ongoing Studies

a. The Contractor shall manage and support data acquisition from dose measurements using soil, archived tissues, milk, teeth, blood, human-like phantoms, computerized treatment planning programs or NCI-developed software, as appropriate, in the estimation of radiation doses to specific organs (or sites within organs) following natural, environmental, man-made, or therapeutic and diagnostic medical exposures for ongoing epidemiologic studies.

1. Assist the NCI Lead Project Investigator in any collection of physical dosimetry so that this information can be applied to the epidemiologic studies of interest as determined by the NCI COR;

2. Manage and support field or radiation equipment testing as necessary for dosimetry (including but not limited to): soil measurements, archived tissues (such as thyroid glands), assessments of teeth or blood for past radiation exposures;

3. Collect radiation and exposure/dose data from medical facilities or other sources as identified by the NCI COR and NCI Lead Project Investigator;

4. As necessary, travel domestically or internationally to hospitals or other sites where study subjects were treated with radiation and consult with medical physicists at the location to determine treatment parameters, as well as manage and support any measurements taken using external beam radiation machines (if still available), or pursue similar machines elsewhere if determined by the NCI COR or Lead Project Investigator to be feasible. The Contractor shall document the typical machine settings used, types of filters employed, and procedures used to treat subjects in the past.

b. The Contractor shall coordinate the dosimetry data previously collected by the NCI. The Contractor shall:

1. Manage and support NCI-developed or standard abstract and summary forms for recording (abstracting) relevant radiotherapy data from individual treatment records collected by NCI and other collaborators;

2. Manage and support training for new or additional abstractors in the collection of required dosimetry data from medical and radiotherapy records in support of NCI epidemiologic studies.

3. Manage and support the collection of data from individual radiotherapy records supplied by the NCI and other collaborators;

4. Manage and support coding schemes developed for abstracted radiotherapy data, e.g. machine settings, type of filters;

5. Manage and support quality review of radiotherapy data collected by the NCI and other NCI collaborators to ensure that necessary and complete data have been collected to allow the calculation of organ doses for individual persons. Identify discrepancies in radiotherapy data so that information gaps can be filled and inconsistencies can be resolved;

c. Manage and support data calculations for estimates of radiation absorbed doses and to allow characterization of uncertainties in doses by:

1. Manage and support calculations for estimates of organ doses for individual subjects for multiple studies as specified by the NCI COR and Lead Project Investigator;

2. Describe comparisons made between the measured doses and the doses calculated from generic dose programs for a sample of patients to validate consistency and accuracy of estimated doses. Document and report the results of comparisons to the NCI Lead Project Investigator;

d. Report organ-specific dosimetry results on individuals in the study.

1. Prepare an edited and documented electronic file of organ doses for individuals in each study as requested by the NCI Lead Project Investigator;

2. Provide a quality score based on completeness of data for each abstracted radiotherapy record, and the source of the radiotherapy information used to determine dose;

3. Prepare a detailed, written description of the final methodology that was employed in the estimation of organ doses and their associated sources of uncertainty;

4. Provide a data file with dosimetry results to the NCI Lead Project Investigator so that NCI can conduct methodologic and sensitivity assessments to evaluate the nature and magnitude of the potential biases and uncertainties in medical dose estimates.

3. Specimen Collection with Samples

The Contractor shall provide support activities involving biological and environmental specimens and laboratory assays, such as specimen collection, repository monitoring, specimen storage, and specimen shipping. Provide staff experienced in the arrangement of all aspects of biologic sample collection, handling, transport, storage, analysis, and information processing.

a. Specimen Collection Manuals and Procedures

1. The Contractor shall develop SOP manuals for the collection, processing, short-term storage, retrieval, packing, shipping, and tracking of a wide range of biological and environmental samples, including (but not limited to) peripheral venous blood, saliva, buccal cells, urine, tumor tissue, teeth, soil, breast milk (for radio-iodines), and other tissue from consenting study subjects.

2. Provide recommendations for storage vials, labels, containers, and other supplies needed for biospecimens collection and storage as well as for shipment (e.g. mail courier services). When recommending vials/containers for specimen storage and shipment, consider what best maintains the integrity of the specimens, which sizes of storage vials would minimize repository storage costs, and what can be shipped in a timely manner. Coordinate with the NCI biorepository to ensure that storage vials and

other containers selected for the study meet their requirements. Coordinate with field investigators and the biorepository to ensure that labels meet their requirements, including bar codes and storage temperature.

3. Order supplies, prepare labels, and deliver to investigators in the field. These supplies should be selected only after obtaining consent from the NCI COR.

4. Provide, manage, and support standard procedures that are adaptable to each site where work is being performed, and utilize standard approaches at all sites where possible in order to minimize sample variation. Document procedures to be followed in field manuals, including quality control procedures.

5. Provide labels with identification numbers for biospecimens or environmental specimens and documentation of the condition of samples.

6. Follow collection and shipment methods to comply with appropriate guidelines for biohazardous material and coordination with various laboratories/institutions.

7. When requested by the NCI COR, the Contractor shall act as a liaison to collect biological or environmental samples for various types of studies in a timely fashion.

8. As requested by the NCI COR, prepare a specimen QC/QA plan, which may include a third party laboratory for periodic specimen testing, addition of replicate samples to assess assay variation, concentration variation to assess assay sensitivity, and plate placement to assess edge effects.

b. Sample Collection, Processing, and Shipping

1. After NCI obtains the necessary and appropriate informed consent, the Contractor shall collect biologic specimens (e.g., peripheral venous blood, teeth, buccal cell mouth wash samples, saliva, breast milk, or environmental samples) from study subjects, which may include domestic or international travel. Process and divide samples, package them as necessary, and ship, transport or deliver them to a designated biorepository or laboratory(ies). Pertinent data (e.g., personal identifiers, collection date, etc.) concerning the specimen donor and processing procedures shall be collected and accompany every biologic specimen.

2. Collect and deliver biologic or environmental samples to laboratories or individuals for storage and/or analysis. For domestic and international studies, develop a shipping list and manifests and coordinate with local PIs and study staff for the transport of study samples from the field to the NCI repository or designated laboratory. Such shipments require that the Contractor arrange for the following: appropriate government clearances required for transferring biologic specimens; appropriate shipping conditions and containers for perishable specimens; close monitoring of the shipment process so that perishable items arrive at their destination in useable condition within the allotted time frame. For international shipments of samples, help

obtain necessary clearances for international shipping, monitor their arrival status and assure that they are appropriately cleared through customs and delivered to the required repository. Perform other general support activities involving collection, storage and/or shipment to laboratories.

3. Report immediately to the NCI COR all irregularities, delays, losses, deteriorations, unplanned thawing, accidents, mishandlings, errors, discrepancies, and inefficiencies connected with any specimen collection, processing, delivery, storage, or testing activity, as well as keep a computerized record of such problems.

4. Assist the NCI COR in obtaining necessary permissions from hospitals and laboratories to collect tumor and adjacent normal samples and other clinical specimens that are no longer needed for patient care as well as collect said specimens for retention and testing at NIH/NCI contracted and collaborating laboratories. Pertinent de-identified data related to the specimens and the donor shall be collected and accompany every biologic specimen.

5. When necessary, provide support for pilot studies so NCI may determine the best methods to collect certain biological specimens at the study sites.

6. Maintain a list of specimens sent to laboratories for a wide range of REB studies that may be a component of a project under this contract.

4. Data Preparation and Processing

a. Provide available information on schemes for coding of medical, radiation dosimetry, occupational, demographic, and genetic coding schemes. Assign and list codes used and document unusual responses.

b. Appropriately code and enter questionnaire responses, medical record data, radiotherapy data, and clinical and laboratory information into computer-readable form. Verify, by independent recoding, at least a 2% sample of the coding (the size of the sample shall be approved by the NCI COR). Recode as necessary. Summarize and describe differences between the two sets of data. Store and maintain data that facilitates monitoring of the field work progress. Ensure quality control and data security. Verify accuracy of data entry by 100% re-entry. Rectify errors and re-enter as needed. Summarize and report nature of the entry errors by comparing differences in the two sets of data.

c. For data received from collaborators, or laboratories, check for readability, completeness and errors, and verify the quality and consistency before preparing analytic files. Consolidate datasets suitable for analyses for transfer to personal computers, as specified by the NCI COR.

d. Maintain adequate backup of study data and secure storage of back up media. Frequency of backup may vary by specific study, but will be determined by the COR. Report verification rates, discrepancy rates, and error rates for data collection, preparation and

keying following the schedule agreed upon with the NCI COR. An unusual problem should be brought to the immediate attention of the NCI COR.

e. Support, maintain, and update secured network, server, computer databases and associated reporting software. Maintain all data on a secure network.

f. Provide editing programs to clean data files, including range and logic checks of data. Edit the data, and correct the computer files where necessary.

g. Update the files with newly acquired data, follow-up data, and error corrections, as requested by the NCI COR. Maintain a clearly documented history of the development and updating of databases.

h. Provide and/or harmonize data sets for transfer to NCI investigators or other collaborators, including consortia, as specified by the NCI COR.

i. Produce reports and analytic files based on collected data as requested by the NCI COR. Provide basic summary statistics and other analyses as specified by the NCI investigator. These may include simple descriptive statistics, such as frequencies or cross-tabulations, or other standard analyses.

j. Avoid proliferation of datasets during conduct of epidemiologic studies. Provide guidelines and procedures for closing out studies and archiving data in an organized manner while retaining critical original data, analysis files, and programs.

k. Provide data sets in response to FOIA requests made to the NCI FOIA office, with special attention to protecting privacy and indirect identification of study subjects.

5. Pilot/Feasibility Studies

a. The Contractor shall support feasibility or pilot studies or other means to enable a decision about undertaking a full study.

1. Upon request of NCI COR, the Contractor shall identify options by which the NCI COR can select unique or special populations. This may include domestic or international travel to the potential study site(s).

2. Obtain necessary information to determine effective study resources (e.g., capabilities of collaborating institutions and laboratories, numbers of eligible study subjects, exposure information) and provide such to NCI COR upon request.

3. Coordinate with the NCI COR or NCI Lead Investigator and investigators at the study sites to identify study subjects who meet the NCI criteria for inclusion in studies and explore the feasibility of alternative selection and sampling schemes as necessary.

4. Report the feasibility of collecting data from hospital records and/or records from radiotherapy departments, and rank their completeness.

5. Report the feasibility of performing linkages to a variety of sources to define vital status, cancer status, medical history, census tract residence, etc. Linking should be done using a quality controlled method that has gone through rigorous testing. Linking should be able to handle partial and mislabeled data.

6. Locate the parties whose cooperation or approval is necessary for implementation of the study (e.g., Federal, state, or local government agencies, including the Department of State; customs officials and other representatives of foreign governments; local institutions such as hospitals, clinics, physicians, private industry, industry associations, labor unions, extramural institutions and collaborators).

7. Compile protocols and complete forms that may be required for various approvals and clearances to undertake studies, such as the DCEG's Senior Advisory Group (SAG), the DCEG's Technical Evaluation of Protocol Committee (TEP), the DCEG's Technical Evaluation of Questionnaires Committee (TEQ), Institutional Review Boards, Office of Management and Budget (OMB), Technology Transfer (TT), and Cooperative Research and Development Agreements (CRADAs). Attend meetings of such committees if requested by the NCI COR.

b. Development of Pilot and Feasibility Study Materials and Procedures

1. The Contractor shall manage and support the preparation, pretesting, printing, and evaluation of data collection forms (e.g., questionnaire, subject enrollment, medical record abstract, pathology and surgical report, anthropometric measurement recording, coding, follow-up, tracking, biospecimen collection, processing, and shipping forms) with guidance, input and approval from the NCI COR. The Contractor shall provide cost estimates for form development, printing, postage, and data entry, comparing costs using different methods, including paper-based or computer-assisted (web-based and/or email-based) methods.

2. When multiple institutions are involved in a multi-center study, the Contractor shall coordinate SOP manuals with the NCI COR approval to assure that the investigation is being conducted in a standardized way at all sites.

3. Provide SOP manuals for medical abstractors, coders, interviewers, phlebotomists, nurses, and other personnel involved in data and specimen collection and management.

4. As requested by the NCI COR, the Contractor shall train and provide materials for interviewers, abstractors, laboratory personnel, medical and radiotherapy record abstractors, coders, or other study personnel for study sites.

5. Provide abstractors, telephone screeners, coders, interviewers, tracers, nurses, phlebotomists, laboratory personnel, field supervisors, and others who are involved in studies in the United States and abroad, and train them on the details of data collection for the specific study on which they are assigned.

6. Work with clinical experts to help train clinical personnel at study sites (including abroad), when necessary.

7. Print and provide manuals for obtaining, handling, and abstracting medical records, radiotherapy records, pathology specimens and reports, and death certificates. Review and code these reports or specimens.

8. Produce or adapt existing schemes of coding with NCI COR approval for categorizing information based on demographic, medical, radiotherapy, occupational, environmental, or other lifestyle factors as well as complex laboratory or genetic data.

9. Translate and manage and support necessary transactions to monitor studies in foreign settings. Translate data collection instruments or manuals into appropriate languages for foreign studies. When requested by the NCI COR, back-translate either a portion of the material or all material into English to ensure that the original meaning of the material has not been changed by the translation.

10. Modify existing or institute new coding schemes for death certificates and medical and pathology records by appropriate nosologists, pathologists, or clinicians in accordance with criteria provided by the NCI COR.

11. Given the similarity of activities across studies, use systems and approaches that can serve as a "shell" or "template" for future work in order to avoid reinventing such systems for each study or project. Manage and support data needs for specific projects and implement an appropriate data management system that allows use by multiple REB projects. This system should facilitate the acquisition of required data, provide for quality control and entry of computer-readable forms, help monitor the progress and accuracy of field work and data acquisition, provide for rapid response and summary characteristics of data, and facilitate construction of data files for analysis.

12. For studies with a clinical component, identify and order supplies and equipment and make arrangement for delivery to the study sites. For international studies, assist with obtaining customs clearance, as needed.

c. The Contractor shall support feasibility studies for collection of dosimetry data to enable a decision about undertaking a full study.

1. As requested by the NCI COR, the Contractor shall provide support necessary for assessments to be made about the ability for NCI to carry out quality dose measurements using soil, archived tissues, milk, teeth, blood, human-like phantoms, computerized treatment planning programs or NCI-developed software, as

appropriate, for the estimation of radiation doses to specific organs (or sites within organs) following natural, environmental, man-made, or therapeutic and diagnostic medical exposures for new epidemiologic studies or to enable NCI dosimetrists to estimate these doses.

2. The Contractor shall support and manage physical dosimetry measures that could be applied to the epidemiologic studies of interest as determined by the NCI COR and Lead Project Investigator (for example in studies of environmental radiation) for the NCI purposes of determining whether such physical measures are feasible to obtain;

3. The Contractor shall manage and support the collection of environmental and biologic data as necessary for dosimetry studies of environmental exposure to radiation (eg: soil measurements, archived tissues (such as thyroid glands), assessments of human teeth or blood for past radiation exposures for the NCI purposes of determining whether such biologic data are feasible to obtain;

4. Collect samples of radiotherapy records so that determination of the necessary elements for dosimetry estimation can feasibly be used from multiple medical facilities;

5. As necessary, travel domestically or internationally to hospitals or other sites where study subjects were treated with radiation and contact medical physicists to assess the availability of treatment parameters. It may be necessary to make initial and limited measurements using external beam machines (if still available), or pursue similar machines elsewhere if determined by the NCI COR or Lead Project Investigator to be feasible. The Contractor shall try to collect data on the typical machine settings used, types of filters employed, and procedures used to treat subjects in the past and report if such data are obtainable and complete.

6. The Contractor shall coordinate the dosimetry data collection for the feasibility assessment. The Contractor shall:

   i. Provide abstract and summary forms for recording relevant data;

   ii. Provide coding schemes for measured or abstracted data;

   iii. Review environmental or radiotherapy data collected by the NCI, other NCI COR specified collaborators, or the Contractor to ensure that necessary and complete data have been collected to calculate organ doses for individual persons. Identify deficiencies in collected data so that information gaps can be filled and inconsistencies can be resolved;

   iv. Provide an evaluation scheme to ensure high quality and completeness of each record that is abstracted or scanned;

v. Describe comparisons made between the measured doses with calculated doses from generic dose programs for a sample of patients to validate consistency and accuracy of estimated doses. Document and report the results of comparisons to the NCI Lead Project Investigator;

vi. Prepare an edited and documented electronic file of abstracted and coded environmental or radiotherapy data and organ doses for each feasibility effort as requested by the NCI Lead Project Investigator;

vii. Provide a quality score based on completeness of the record for each measurement or abstracted radiotherapy record, and the source of the information used to determine dose;

viii. Provide a detailed, written description of the final methodology used for organ dose estimation and associated sources of uncertainty for each feasibility effort, in order for the NCI Lead Project Investigators to assess the dose estimation process and its associated uncertainties;

ix. Provide a literature review of dose estimates from similar study populations for the proposed feasibility effort as requested by the NCI COR;

TASK AREA III – Support Services for New Full Studies

The Contractor shall provide support for new study if the pilot/feasibility study warrants a full study.

There are two major sections to Task Area III:

1. Subject Identification, Selection, and Tracing
2. Data Collection

1. The Contractor shall support and manage subject identification, selection, and tracing

a. Coordinate with investigators at the study sites which may include domestic or international travel, to implement methods as approved by the NCI COR for identifying study subjects who meet the NCI criteria for inclusion in studies.

b. Based on criteria provided by the NCI COR, use methods to identify appropriate control series for use in case-control studies. This could include a variety of different types of controls, including (but not limited to) those controls from hospitals or clinics, random-digit dialing, area surveys, employer personnel or labor union records, or population rosters. Other techniques may be required. When methods such as random-digit dialing are performed, clear documentation shall be kept so that precise response rates can be determined for all phases of the telephone screening, and so that reasons and demographic characteristics can be summarized for subjects who refuse to participate or who are lost to follow-up.

c. Acquire appropriate population rosters or files from sources such as motor vehicle departments and Medicare files to identify selected series of potential study subjects. For domestic and international studies, coordinate with local agencies and institutions, such as the census bureaus, to identify an optimal sampling frame or population roster for the selection of study subjects.

d. Based on criteria provided by the NCI COR, trace study subjects to contact them to decide eligibility, introduce the study, ascertain their vital status, invite participation, establish cancer diagnoses or obtain other information necessary to meet study objectives. For deceased or incapacitated subjects, it may be necessary to locate and interview next-of-kin or other proxy respondents.

e. Assemble death certificates and records on cancer incidence for coding by appropriate nosologists, pathologists, and clinicians.

f. For cases in previously completed or ongoing NCI studies, obtain follow-up information from medical records and mortality databases. Arrange for National Death Index and National Death Index Plus searches for United States study populations and verify that the correct subjects have been matched to the death records. This may require additional follow-up with state vital records departments to obtain hard copies of death certificates.

The Contractor shall be responsible for how best to provide payment for death certificates.

g. Monitor subject enrollment and response rates. As needed, identify strategies or systems to improve case ascertainment and subject participation rates, in particular for minority and underserved populations.

h. Remove personnel identifiers, create study participant IDs, retain the key, and use a psuedonymized ID for data sharing/analysis as needed.

2. The Contractor shall manage and support data collection

a. The Contractor shall manage, support, and oversee field activities in the U.S. and abroad, which may include travel that results in the acquisition of data with appropriate identifiers.

b. The Contractor shall manage and support the abstraction, scanning, photocopying, or otherwise obtaining electronic copies of records (medical records, radiotherapy records, cancer treatment records, vital records, or employment records). The Contractor shall maintain quality control over the abstracting or copying process. The Contractor shall verify a sample of abstracts by independent re-abstraction.

c. Once NCI has obtained the necessary IRB and OMB approvals, the Contractor shall support and manage interviewing subjects or surrogates using mail, telephone, computer-assisted, or personal interviews. Tape the interviews if specified. If requested, verify a sample of completed questionnaires by re-interviewing subjects. If verification indicates a problem, develop and implement ways to correct the problem.

d. The Contractor shall obtain approvals to link data with state cancer registries to substantiate information on cancer diagnoses among study subjects. As requested by the NCI COR, obtain record linkage data from population-based in-patient and cancer registries in the United States or abroad for analytic studies. The Contractor shall institute processes to standardize information across cancer registries to enable the pooling of data.

e. The Contractor shall institute tracing management systems to maximize participation and reduce loss rates for all data collection efforts. The Contractor shall support and manage systems to describe document control for best name, date of birth, last known address, and last known vital status with appropriate dates.

f. The Contractor shall obtain all necessary pathology reports or other reports of cancer from hospitals for study subjects and provide English translations of selected foreign reports and documentation of pathologic diagnoses, as requested by the NCI COR.

g. The Contractor shall manage and support tracking systems that can be utilized by multiple REB projects to monitor the incoming flow of data, editing of data, and

correcting data, which can be subsequently summarized into descriptive reports to avoid duplication of effort across projects.

h. The Contractor shall make all necessary arrangements for transfer of data, including electronic transfers, and shipment of other material from (and to) the United States and to (and from) the country where the study is being conducted for all international studies supported by this contract.

i. The Contractor shall provide QA support that may include validation of exposure, treatment and/or disease histories obtained in interviews by obtaining original records. This includes maintaining a management tracking system for the retrieval of such records.

j. When requested by the NCI COR, the Contractor shall manage and support appropriate scientific and medical expertise to collect data, such as abstracting data from complex pathology and/or radiotherapy reports. When requested by the NCI COR, the Contractor shall act as a liaison to collect clinical and/or radiotherapy information for various types of studies in a timely fashion.

k. Provide logistical support for scientific meetings, which may include publication and/or copying of proceedings.

TASK AREA IV – Phase Out

The Contractor shall develop and submit a draft final transition plan at the beginning of year 5, which will describe the Contractor's strategy for transferring work from this contract to a successor contract, in the event a final transition would be required. The plan must include a detailed description of the procedures to be used to insure the orderly and timely transition of studies; transfer of relevant electronic and hard copy files, records, materials and documentation, as appropriate. The draft final transition plan will be revised, if necessary, and the draft final transition plan will become the final transition plan upon approval of the COR. The approved final transition plan shall be followed to ensure an orderly, secure, efficient, and expedient transition of all contract activities by the contract completion date.

The Contractor shall attend orientation briefings organized by the new Contractor. The Contractor shall ensure that any transitioning of staff on tasks on the current studies will be performed with minimal impact on support delivery and shall be discussed with the NCI COR before such transitioning occurs in cases where it may be expected to negatively affect performance, budget, and/or delivery schedule. Problems anticipated or encountered shall be immediately communicated to the COR and an approved resolution pursued. Should a final transition be required, the transition period shall be from August 20, 2019 through September 19, 2019.

Sample Task Order 0001
Request for Proposal (TO-RFP)
RFP N02CP41010-32

Task Order Title
Phase-In

Statement of Work

Background:
This acquisition is the re-competition of the National Cancer Institute (NCI) Epidemiologic Studies of Radiation and Cancer Risk, which provides Radiation Epidemiology Branch (REB) support services. The requirement was re-competed in 2009, and resulted in an award to Research Triangle Institute (RTI) (N02-CP-90017).

A Contract phase-in as described in the contract statement of work, Task Area I, would be required if the incumbent Contractor, RTI, is not the successful awardee.

Objectives:
To successfully transfer from the incumbent to the new awardee.

Technical Requirements:

Upon award, the draft initial transition plan shall be revised, if necessary, and the draft initial transition plan submitted with the Contractor's proposal will become the final initial transition plan upon approval of the Contracting Officer's Representative (COR). The initial transition plan shall delineate the following:

- transition activities to be undertaken
- timelines for the completion of each transition activity
- staff to be assigned

Resource materials provided by the incumbent Contractor to the Contractor will include:

- Study protocols
- Standard Operating Procedures
- Data collection forms
- Coding manuals
- Data files – electronic and hard copy (as approporiate)
- Decision logs
- List of critical data files
- QC/QA plan
- Tracing files
- All other relevant study documentation

The final initial transition plan shall be followed to ensure an orderly, secure, efficient, and expedient transition of all contract activities. The Contractor shall conduct orientation briefings

for NCI Lead Project Investigators and Contractor Key Personnel and participate in one full-day contract initiation meeting with:

- NCI COR
- Contracting Officer
- Other NCI staff designated by the NCI COR
- Contractor personnel
- Incumbent Contractor personnel

Should an initial transition be required, the transition period shall be from August 20, 2014 through September 19, 2014.

Reporting Requirements and Deliverables

The Contractor shall submit the following reports:

A. The final Phase in project plan is due within 10-days of the Task Order Award. The final copy shall be sent to the COR and Contracting Officer electronically (ncibrancheinvoices@mail.nih.gov).

Type of Task Order

Cost Reimbursement

Period of Performance of Task Order

Task Order One (0001) period of performance is August 20, 2014 to September 19, 2014.

Technical Proposal Instructions

Technical Proposal shall not exceed 10 pages in length. Include the same information required for the Business Proposal Cover Sheet for the Technical Proposal Cover Sheet.

A detailed work plan must be submitted indicating how each aspect of the Statement of Work is to be accomplished. Your technical approach shall be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal shall reflect a clear understanding of the nature of the task order being under taken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided that will demonstrate your understanding and management of this task.

Describe the experience and qualifications of personnel who will be assigned for direct work on this task. Provide information that shows recent experience with similar programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this task.

Resumes of all personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications. If an individual's resume was submitted with your original technical proposal, you do not need to include it again here. Only include resumes of individuals where one was not previously provided. Resumes do not count towards the page limit specified above.

Business Proposal Instructions

For Business Proposal COVER SHEET submit the following:

- Solicitation number
- Task Order RFP Number
- Name, address, email and telephone number of Principal Investigator
- Date of submission
- Name, title, address, email, telephone and signature of authorized Business Representative (person authorized to sign contracts on behalf of the organization)

Budget:

- Provide a Summary of Proposed cost and/or price (Excel sheet); profit or fee (as applicable); and total.
- Provide a brief narrative justifying the proposed costs by cost item.

Sample Task Order 0002
Request for Proposal (TO-RFP)
RFP N02CP41010-32

Task Order Title
REB Core Support Services

Statement of Work

Background:
This acquisition is the re-competition of the National Cancer Institute (NCI) Epidemiologic Studies of Radiation and Cancer Risk, which provides Radiation Epidemiology Branch (REB) support services. The requirement was re-competed in 2009, and resulted in an award to Research Triangle Institute (RTI) (N02-CP-90017).

The Contractor shall provide REB support services as described in the contract statement of work, Task Area II.

Objectives:
To ensure that REB is fully supported.

Technical Requirements:

Please see Task Area II – "REB Core Support Services" of the SOW for the entire technical requirement.

The REB Core Support Services consists of the provision of broad-based, centralized, and fully integrated operational, administrative, regulatory, and logistical support services to all REB studies.

It is anticipated that the following studies will require support under Task Order 2:

a. Ongoing studies:
   i. Second Cancers After Breast Cancer in Kaiser HMO
   ii. Second Cancer Risk Following Chemotherapy and Radiotherapy for Retinoblastoma
   iii. U. S. Radiologic Technologist (USRT) Cohort studies: Dose Reconstruction
   iv. Dose Reconstruction and Health Effects of *In-utero* and Early-life Radiation Exposure (Chernobyl–related studies)
   v. Medical Radiation Dosimetry for Epidemiologic Studies
   vi. Support state-of-the-art computer program for individual organ dose calculations from radiological accidents or terrorist events
   vii. InterLymph Subtypes International Project
   viii. Periconception Folic Acid Supplements and Other Postulated Risk Factors for Pediatric Leukemia and Other Childhood Cancers: A Record-Linkage Study in a Chinese Cohort
b. Pilot/Feasibility Study:
   i. US Veterans "Weathermen" Biodosimetry Study

Reporting Requirements and Deliverables
The Contractor shall submit the following reports:

A. Monthly Task Order Progress Report
B. Monthly Task Order Expenditure Report
C. Draft Final Task Order Report
D. Draft Final Task Order Expenditure Report
E. Final Task Order Report
F. Final Task Order Expenditure Report

Type of Task Order
Cost Reimbursement

Period of Performance of Task Order
Task Order Two (0002) period of performance is six (6) months beginning on either August 20, 2014 or September 20, 2014, depending on whether a phase-in period is required.

Technical Proposal Instructions
Technical Proposal shall not exceed 100 pages in length. Include the same information required for the Business Proposal Cover Sheet for the Technical Proposal Cover Sheet.

A detailed work plan must be submitted indicating how each aspect of the Statement of Work is to be accomplished. Your technical approach shall be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal shall reflect a clear understanding of the nature of the task order being under taken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided that will demonstrate your understanding and management of this task.

Describe the experience and qualifications of personnel who will be assigned for direct work on this task. Provide information that shows recent experience with similar programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this task.

Resumes of all personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications. If an individual's resume was submitted with your original technical proposal, you do not need to include it again here. Only include resumes of individuals where one was not previously provided. Resumes do not count towards the page limit specified above.

Business Proposal Instructions

For Business Proposal COVER SHEET submit the following:
- Solicitation number
- Task Order RFP Number
- Name, address, email and telephone number of Principal Investigator

- Date of submission
- Name, title, address, email, telephone and signature of authorized Business Representative (person authorized to sign contracts on behalf of the organization)

Budget:
- Provide a breakdown of Proposed cost and/or price (Excel sheet); profit or fee (as applicable); and total.
- Provide a brief narrative justifying the proposed costs by cost item.

Sample Task Order 0003 is only for evaluation purposes. This sample task order will not be awarded when the IDIQ contract is awarded.

Sample Task Order 0003
Request for Proposal (TO-RFP)
RFP N02CP41010-32

Task Order Title

Support Services for New Full Studies: "Second cancer risks after intensity modulated radiation and proton therapy."

Statement of Work

Background: Intensity modulated radiation therapy (IMRT) is a newer and rapidly expanding approach to the planning and delivery of radiotherapy. IMRT allows dose to be concentrated in the tumor volume and so should result in better tumor control and reduction of acute toxic effects in surrounding organs. However, because more monitor units and more fields are used than in conventional radiotherapy, the result is a larger total-body radiation dose and increased dose to organs outside the radiation fields. Hence, the reduction in acute toxic effects may be at the cost of increased risks of second malignancies. To date there have been no direct studies of the long-term second cancer risks from IMRT use. Proton therapy is also rapidly expanding and many similar concerns exist for this alternative therapy, especially exposure to neutrons as a by-product. The purpose of the study is to identify the risk of second cancers in patients who were treated with proton therapy and with IMRT.

Objectives: Construct a cohort of 5,000 adult patients treated with IMRT or proton therapy**.**

Technical Requirements:

Please see Task Area III – "REB Core Support Services" of the SOW for the entire technical requirement.

It is anticipated that the following work will be required to support this study:

1. Contact hospitals where patients were treated with IMRT or protons and secure approvals to conduct the study. Hospitals may be in the United States or elsewhere (Assume that one hospital is in Germany and one is in Japan).
2. Identify patients who survived at least 2 years after treatment with IMRT or protons, and abstract medical records (e.g., type of cancer, age at treatment, year of treatment) onto paper forms or if available, obtain data from electronic medical records.
3. Abstract or photocopy radiotherapy records (e.g., type of radiotherapy, dates of treatment) or if available, obtain radiotherapy data from electronic medical records.
4. Follow up patients for second cancers by searching medical records and linking with state cancer registries and the National Death Index, or national cancer registries if the hospital is located outside the US.
5. Determine vital status of patients.

6. Obtain confirmation, i.e. pathology or histology reports, for the second cancers.
7. Prepare an edited, analytic datafile of the cohort.

Reporting Requirements and Deliverables
The Contractor shall submit the following reports:

A. Monthly Task Order Progress Report
B. Monthly Task Order Expenditure Report
C. Draft Final Task Order Report
D. Draft Final Task Order Expenditure Report
E. Final Task Order Report
F. Final Task Order Expenditure Report

Type of Task Order
Cost Reimbursement

Period of Performance of Task Order
Task Order Three (0003) period of performance is three years.

Technical Proposal Instructions
Technical Proposal shall not exceed 25 pages in length. Include the same information required for the Business Proposal Cover Sheet for the Technical Proposal Cover Sheet.

A detailed work plan must be submitted indicating how each aspect of the Statement of Work is to be accomplished. Your technical approach shall be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal shall reflect a clear understanding of the nature of the task order being under taken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided that will demonstrate your understanding and management of this task.

Describe the experience and qualifications of personnel who will be assigned for direct work on this task. Provide information that shows recent experience with similar programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this task.

Resumes of all personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications. If an individual's resume was submitted with your original technical proposal, you do not need to include it again here. Only include resumes of individuals where one was not previously provided. Resumes do not count towards the page limit specified above.

Business Proposal Instructions

For Business Proposal COVER SHEET submit the following:
- Solicitation number

- Task Order RFP Number
- Name, address, email and telephone number of Principal Investigator
- Date of submission
- Name, title, address, email, telephone and signature of authorized Business Representative (person authorized to sign contracts on behalf of the organization)

Budget:

- Provide a breakdown of Proposed cost and/or price (Excel sheet); profit or fee (as applicable); and total.
- Provide a brief narrative justifying the proposed costs by cost item.